

REMARKS

Claims 1-16 are now pending, where claims 1, 2, 5, 6, 13 and 16 are amended, and claims 17 and 18 are canceled.

Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully submit that the above amendments to claim 13 overcome this rejection since claim 13 now depends from claim 4, which provides proper antecedent basis for the feature "the inflatable chamber". Accordingly, withdrawal of all rejections under 35 U.S.C. § 112 is respectfully requested.

Claims 1-5 and 8-18 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Barath in view of Lin et al. Claims 6 and 7 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Barath in view of Lin et al. and further in view of Lemelson et al.

Amended independent claims 1 and 16 are directed to devices for administering a composition in a wall of a duct of a human or animal body. The claimed devices comprise novel combinations of features, including means for entering an inner surface of the duct wall and making at least one opening in the form of a pinprick having a diameter from approximately 0.05 mm to 1.0 mm in a thickness of the wall, and a dispenser means for placing the composition in contact with the at least one opening. Applicants respectfully submit that the features set forth in these claim are disclosed in the originally filed specification at page 9, lines 8-10.

The Office Action relies upon Barath for a disclosure of a balloon catheter 2 with sharp longitudinal processes or cutting edges 6 that protrude parallel with the longitudinal axis of the surface of the balloon such that when the balloon is inflated, the cutting edges penetrate the vessel wall to make longitudinal cuts. Barath further discloses a device with the cutting means 6 within the lumen of a conventional balloon catheter 28 such that after making longitudinal cuts in the vessel wall, the balloon catheter 28 is moved into place and inflated to dilate the vessel. The Office Action recognizes that Barath does not disclose that balloon catheter 28 is a medication-dispensing catheter. Lin et al. is relied upon for a disclosure of a medication dispensing catheter with a balloon 10 having outlet 20 through which medication is delivered. The Office Action contends that it would have been well known to one of ordinary skill in the art to replace the balloon catheter 28 in the Barath device with a medication dispensing catheter as taught by Lin et al. to deliver medication to the vessel wall.

Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness since there is no suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify the Barath device as suggested by the Office Action to include a dispensing catheter as taught by Lin et al. In fact, Applicants respectfully submit that the proposed modification of Barath to include the medication dispensing catheter taught by Lin et al. would render the prior art inventions in both Barath and Lin et al. unsatisfactory for their intended purposes.

In Lin et al. the balloon 10 has an inner balloon wall 12, an outer balloon wall 14, and dividers 17 which define channels or conduits 16 therebetween. Each of the channels 16 has a proximal opening 18 into which medication enters, and each channel terminates in an outlet 20 on the outer balloon wall 14, through which medication 19 is delivered. Applicants respectfully submit that this type of balloon would not work in the device disclosed in Barath since the balloon catheter disclosed in Barath folds up around the cutting edges to prevent injury of the vessel during delivery, and then the balloon is inflated to allow the cutting edges to penetrate into the vessel. Inflation of the balloon disclosed in Barath requires the buildup of a working pressure within the balloon in order to drive the cutting edges radially outward into the vessel. The configuration of the balloon disclosed in Lin et al., wherein the balloon has an inner balloon wall, an outer balloon wall and dividers which define conduits therebetween, would be unsatisfactory for this intended purpose in Barath. Accordingly, Applicants respectfully submit that neither Barath nor Lin et al. provide any suggestion or motivation to make the proposed modification.

Independent claims 1 and 16, and hence dependent claims 2-15, are further patentable over the prior art references of record since none of the references of record disclose or suggest a device for administering a composition in a wall of a duct of a human or animal body, which device comprises a novel combination of features including means for entering an inner surface of the duct wall and making at least one opening in the form

of a pinprick having a diameter from approximately 0.05 mm to 1.0 mm in a thickness of the wall.

For at least the above reasons, Applicants respectfully submit that amended independent claims 1 and 16, are patentable over the applied prior art references, whether the references are considered individually or in combination. Dependent claims 2-15 are also patentable for at least the same reasons as discussed above with regard to independent claims 1 and 16, and for the additional features they recite. Accordingly, it is respectfully submitted that claims 1-16 are in condition for allowance.

Prompt issuance of a Notice of Allowance is earnestly solicited. In the event that any questions arise regarding this communication or the application in general, please contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By: William O. Trousdel
William O. Trousdel
Registration No. 38,637

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620